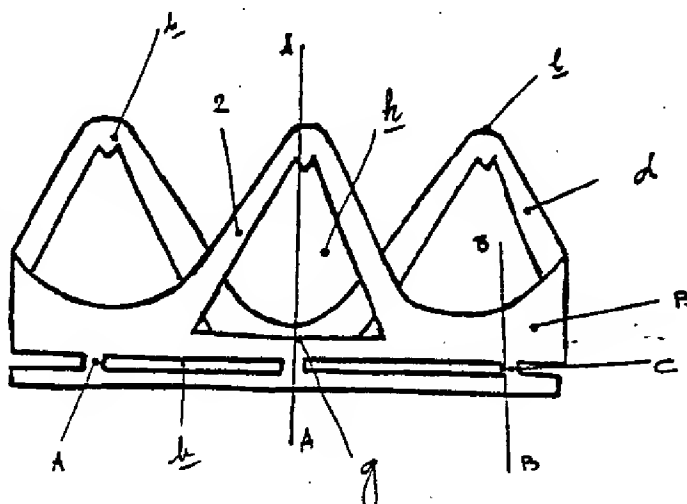




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| (21) International Application Number: PCT/RO81/00009 (22) International Filing Date: 2 December 1981 (02.12.81) (31) Priority Application Number: 103.294 (32) Priority Date: 4 February 1981 (04.02.81) (33) Priority Country: RO (71) Applicant (for all designated States except US): SPITALUL CLINIC FUNDENI [RO/RO]; Sos. Fundeni 258, Sector 2, cod. 72435 Bucuresti (RO). (72) Inventors; and (75) Inventors/Applicants (for US only): POP D. POPA, Ioan [RO/RO]; Str. Muzeul Zambaccian Nr. 29, Sector 1, cod. 71277 Bucuresti (RO). GHERGHICEANU, Dan [RO/RO]; Str. Ing. Cucu Starostescu Nr. 10, Sector 1, cod. 71277 Bucuresti (RO). DOBRE, Mircea [RO/RO]; Str. Drumul Taberei Nr. 109, Bl. A7, Sector 6, cod. 77641, Bucuresti (RO). | | (74) Agent: OFICIUL DE BREVETE SI MĂRCI PENTRU STRĂINĂTATE ROMINVENT; Bd. n. Bălcescu Nr. 22, Sector 1, 70122 Bucuresti, (RO). (81) Designated States: DE (European patent), FR (European patent), SU, US. Published <i>With international search report.</i> |
| (54) Title: CARDIAC VALVULAR BIOPROSTHESIS AND THE PROCEEDING OF ACHIEVEMENT (57) Abstract <p>A cardiac valvular bioprosthesis is made of a biologic material (aortic valve of wild boar, bear or other animal) of a special structure which is applied on metallic support (2) or plastic material by means of a connection stratum (3) of knitted textile material and the fixation on the heart is accomplished by means of a ring (4) of textile material, plastic or silicone rubber. The support (2) for the bioprosthesis is made of a basis (A) and a superstructure (B). The basis (A) has a circular form with a diameter according to the diameter of the prosthesis which must be replaced and, on the circumference, presents a tube (b) of 1-2 mm, interrupted by some resistance pills (c), of which some in the middle of the flanks (d) and the others in the middle of the curve between the two flanks. Further is described a proceeding of achievement of cardiac valvular bioprosthetics.</p> | | |



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Cardiac valvular bioprosthesis and the proceeding of achievement

1. TECHNICAL FIELD

The present invention relates to a cardiac valvular bioprosthetics, used in cardiac valvular replacements and to the proceeding of achievement.

2. BACKGROUND OF PRIOR ART

Mettallic valvular prosthetic of different constructions are known.

The drawback of these prosthesis that the beares are obligatory submitted to a chronical anticoagulant treatment.

The bioprosthetics made from a pericardium of calf, human dura mater and broad fascia are more known.

The drawback of these prosthesis is: their cuspa does not present an adequate anatomical form and their resistance is reduced.

The valvular bioprosthetics from an aorta of domestic pig are also known. The drawback of these bioprosthetics is that, due to the short fibres with great fibrillar spaces for the fat storehouse, they present a more reduced resistance in time.

3. BRIEF SUMMARY OF INVENTION

The cardiac valvular bioprosthetics, in accordance with the invention, remove the above drawback, in a view to obtain a greater resistance by using as biological material, an aortic valva from wild boar, bear or other animal, with a special structure of the



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tissues, applied on a metallic support or plastic material by agency of a relation stratum from knited textile material and the heart fixation making by agency of a burelat ring.

The biologic material contains: an aortic valva of wild boar, bear or other animal, taked with the aortic wall and interventricular septum, immediatly after the animal sacrifice.

The aortic valva of wild boar is a valva with three depth cuspaes which achieve some nests which much prolabe under the horizontal plan which passes through the valvular ring. To translighting, the cuspaes appear semitransparent, the maximum tranparence being to the center cuspaes. Also, the presence of dense fasciculae of fibres is observed in length of cuspa, between comisures, approximately parallel with the cuspa edge which is free, the length of these fibres and the parallel sitting (small spaces between the fibres) giving to the tissue an incresed resistance and elasticity, tissue submitted to a very intensive mechanic requirement.

The support for the valva is made from a basis and a superstructure. The basis has a circular form with the diameter depending of the valva diameter which must be replaced (between 1-2mm), interrupted by resistance pillars from which someones, disposed in the middle of flankies basis and, the others, in the middle of curve between two flankies.

The superstructure is formed from three flankies like an isoscel triangle, disposed at 120° , between the superior tips.

The passing from a tip to the other, is formed on a curve which fidclly follows the natural form of biologic valva which must be mounted on the support.

Each triangle flankies is disposed with the small side on the support basis, the opposite tip to basis is rounded and, in interior, has a window of the same form and a prominence for fixing the seam.

The burelat ring can be made from knited textile material, plastic material or siliconal material.

The proceeding of achievement of cardiac valvular bioprosthetic consists in taking the biologic material from the wild boar, immediately after sacrifice. They take the aortic valva with the aortic wall



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and a side of the interventricular septum, it is washed in physiologic serum in a view to eliminate the blood, the muscular fibres are eliminated from the septal cuspa and, from the aorta, the surplus of tissue. Swabs are introduced in cuspaes for maintaining the form and they are introduced in keeping solutions and sterilization, they are stored in containers at 6-12° and after 48h, the biologic material is pulled and prepared for mounting on the metallic support.

The preparing consists in eliminating all muscular fibres from the cuspaes surface and cutting the aortic wall in concordance with the form of superior edge of metallic support, dressed with a textile stratum.

The metallic support is separately prepared by dressing with knited textile material with a tubular form, introduced from downwards to upwards through the metallic support and after, the superior edge of the tube (textile material) is bended over the flange tips and is pulled under the inferior edge of support with 8-10mm shorter than the other edge of inferior textile tube.

Further on, the surplus of textile material is remove, comprised between flange tips and the edge must be cut with thread from the exterior to the interior of edges for being plugged.

The exterior cylinder is fixed in few points (six) of the basis of metallic support, the surplus is cut and bended over its edge, the burelat ring is applied and fixed in few points on the support basis (through the textile stratum and the tube of support basis). The edge of the interior cylinder must be bended over the burelat ring and cut around with a permanent thread.

Further on, the biologic material, previously prepared on the dressed support is mounted by cutting with two threads and its introduction being made through the support interior. A seam is made between the aortic valvular ring and the inferior edge of the dressed metallic support, the second seam is made between the prepared aortic wall and the superior edge of the support. After all these, a band from the same knited textile material is applied on the superior edge of dressed support and the biologic material thus sewed so that it covers the seam between the biologic material and



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support for protecting the seam.

Until its using, all make proceeding is kept in keeping solution and sterilization, accomplishing a sterile medium.

4. MEANS OF INDUSTRIAL ACHIEVEMENT

The cardiac valvular bioprosthetics, in accordance with the invention, can be achieved on an industrial or semiindustrial way providing, first at all, the source of biologic material as well as the means necessary for its make. For obtaining the prosthesis replacements in man, it is necessary to make their tests by some apparatus which determine their resistance and their hidrodynamic performances.

5. SHORT PRESENTATION OF THE FIGURES

We illustrate an achievement also regarding the figures 1-4 representing:

- fig.1-sight with section through bioprosthetics
- fig.2-sight with section through the flanky tip A-A
- fig.3-sight with section B-B
- fig.4-sight from face of metallic support

6. DETAILED DESCRIPTION OF INVENTION

The cardiac valvular bioprosthetics, in accordance with the invention, is made from a biologic material 1 (aortic valva of wild boar, bear or other animal) with a special structure which is applied on metallic support 2 or plastic material by agency of a stratum 3 for contact from knited textile material and the fixation on the heart accomplishing by agency of a burelat ring 4 from textile material, plastic material or siliconic rubber.

The aortic valva of wild boar is a prosthesis with three deep cuspa a, formed from dense fasciculae of fibres on the cuspa length between comisures approximately parallel with the free edge of it.

The support 2 for the prosthesis 1 is made from a basis A and a superstructure B.



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The basis A has a circular form with a diameter depending of prosthesis diameter which must be replaced (between 15-33mm) and on the circumference, it presents a tube b, 1-2mm, interrupted by some resistance pills c from which someones in the middle of the flangeies d and the others in the middle of the curve between the two flangeies.

The superstructure B is formed by three flangeies d with an isoscel triangle form, disposed at 120° between the superior tips e. The passing from a tip to the other is made on a curve f which fidelly follows the natural form of the biologic prosthesis which must be mounted on the support.

Each flangey d is set with the small side g on the basis A, the tip opposite to the basis, is rounded and, in interior, presents a window h of the same form and a prominence i for fixing the seam material.

The proceeding of achievement of cardiac valvular bioprosthethics consists in taking the aortic prosthesis 1 with the aortic wall j and a side from interventricular septum k of the wild boar, they wash it in physiologic serum for blood removing, the muscular fibres of septal cuspaes are eliminated and, also, the tissue surplus of the aorta. The swabs are introduced in cuspaes for the form maintaining and they are introduced in keeping solutions and sterilization with glutaraldehyde 0,625, tamponed with phosphat at Ph 7,2-7,4. They are deposited in containers at $5-12^{\circ}$ C, after 48h, the biologic material is taken and prepared for its mounting on the support 2.

The preparing consists in eliminating the muscular fibres of the cuspaes surface g and in cutting the aortic wall j in accordance with the superior edge of the dressed support 2 with the stratum 3 from textile material. The metallic support 2 is separately prepared by dressing with knited textile material 3 of tubular form, introduced from downwards to upwards through the support 2.

The material 3 is bended over the tips e and the tube 1 pulled under the inferior edge of a support 2 with 8-10cm shorter than the end m of a material 3. Further on, the material surplus comprised between the flangeies d and the edges are cut with thred from the exterior to the interior of the edges for being plugged.



The cylinder 1 is fixed in few points(six) on the basis A, the surplus is cut and it is bended over the edge, the burelat ring 4 is applied and fixed in few points on the basis A. The cylinder edge m is bended over the ring 4 and they cut around with a permanent thread.

Further on, the biologic material 1 is mounted and previously prepared on the support 2 by sewing with two threads, its introduction being made through the interior of the support 2.

A seam is made between the aortic valvular ring and the inferior edge of the support 2 and the second seam, between the prepared aortic wall j and the superior edge of the support 2. After all these, a band 5 from the same knited textile material is applied on the superior edge of the dressed support 2 and the biologic material j so cut that it covers the seam from the biologic material j and the support 2 for its protection.

All proceeding of achievement is made in sterile medium.

Until its utilisation, the prosthesis must be kept in keeping solution and sterilisation.

7. ADVANTAGES

The cardiac valvular prosthesis and the proceeding of its achievement present the following advantages:

- a greater resistance in time
- no requires a permanent anticoagulant treatment
- the employment of this prosthesis is indicated specially for certain categories of patients as: young women, ulcer, with disorders of sanguine chrasa, special social circumstances (bradipsychics, difficult access to medical assistance), hypertensive patients(to whom the prosthesis of pig are unadvisable).



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CLAIMS

1. Cardiac valvular bioprosthesis, characterized by the employment as biologic material of an aortic valva(1) of wild boar, bear or other animal (for obtaining a greater resistance in time) with dense fasciculae of fibres on the cuspa length(a) between comisures, approximately parallel with the free edge of this, the length of these fibres and the parallel dispersion giving to the tissue, an increased resistance and elasticity which can resist to mechanic demands of a great intensity, the prosthesis being applied on a metallic support(2) or plastic material by agency of a connection stratum(3) from knited textile material and the fixation on the heart being made by agency of a burelat ring(4) from textile material, plastic or siliconic rubber.

2. Bioprosthesis, in accordance with the claim 1, is characterized by: a metallic support(2) formed from a basis (A) and a superstructure (B) from which the basis(A) has a circular form with a diameter according to the prosthesis diameter which must be replaced and, on the circumference, it presents a tube(b) of 1-2mm, interrupted by some resistance pills(e), the superstructure(B) of a support(2) being formed from three flangeies(d) in an isoscel triangle form, disposed at 120° between the superior tips(e), the coupling between the tips being made on a curve(f) similar to natural biologic valva, each triangle flange being set with the small side(g) on the support basis, the tip(e), opposite to basis, is rounded and, in interior presenting a window(4) with a same form and prominence(i) for fixing the material of seaming.

3. The achievement proceeding of cardiac valvular bioprosthesis, according with claims 1, 2 is characterized by: for its make, the aortic valva(1) is taken, also an aortic wall(j) and a side of interventricular septum, immediately after the animal sacrifice, it is washed with physiologic serum for blood removing, the muscular fibres being eliminated from the septal cuspa and the tissue surplus from the aorta, swabs are introduced in cuspae, after, they are introduced in a keeping solu-

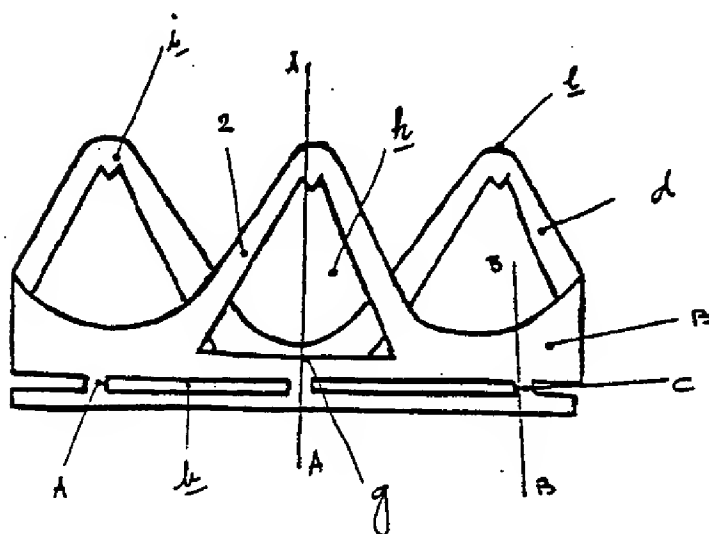
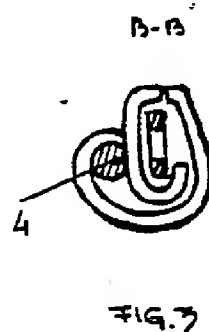
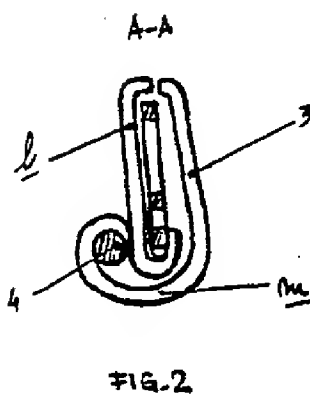
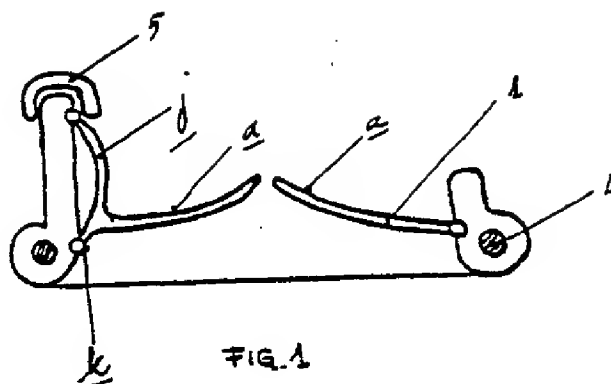


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tion and sterilization, they are deposited in containers at 6-12° C and after 48 h, the biologic material must be pulled and the aortic wall(j) peeled, the metallic support(2) is separately dressed with a tubular knited textile material(3) which bends over the flange tips(d), they cut and sew, the exterior cylinder must be fixed, the burelat ring(4) is applied, after which the interior cylinder(m) bends and it is sewed on the support thus achieved, they applied with two seams the prepared biologic material(1) after which, on the superior edge of support, dressed with a fixed biologic material (j), a band(5) from knited textile material, is applied for the seam protection.



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INTERNATIONAL SEARCH REPORT

International Application No PCT/RO 81/00009

| | | |
|---|--|---|
| I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) * | | |
| According to International Patent Classification (IPC) or to both National Classification and IPC | | |
| A 61 F 1/22 | | |
| II. FIELDS SEARCHED | | |
| Minimum Documentation Searched * | | |
| Classification System | Classification Symbols | |
| IPC | A 61 F 1/22 | |
| Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched * | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT 14 | | |
| Category * | Citation of Document, 14 with indication, where appropriate, of the relevant passages 17 | Relevant to Claim No. 15 |
| X | US - A - 3 570 014, published 1971, March 16 (HANCOCK) -- | 1, 2, 3 |
| Y | GB - A - 1 253 442, published 1971, Nov. 10 (CUTTER LABORATORIES INC) -- | 1, 2, 3 |
| Y | FR - A1 - 2 451 189, published 1980, Oct. 10 (LIOTTA) -- | 1, 2, 3 |
| Y | FR - A1 - 2 355 492, published 1978, Jan. 20 (LIOTTA) -- | 1, 2, 3 |
| Y | US - A - 4 106 129, published 1978, Aug. 15 (CARPENTIER) -- | 1, 2 |
| Y | FR - A - 2 038 843, published 1971, Jan. 8 (DASSAULT) -- | 1, 2 |
| <p>* Special categories of cited documents: 13</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> | | |
| IV. CERTIFICATION | | |
| Date of the Actual Completion of the International Search * | | Date of Mailing of this International Search Report * |
| 08-03-1982 | | 15-04-1982 |
| International Searching Authority * | | Signature of Authorized Officer 19 |
| Austrian Patent Office | | <i>John J. ...</i> |

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

| | | |
|---|--|-----|
| X | <u>GB - A - 1 264 471</u> , published 1972, Feb. 23 (HYPODERMIC SERVICES LTD) -- | 1,2 |
| Y | <u>GB - A - 1 264 472</u> , published 1972, Feb. 23 (HYPODERMIC SERVICES LTD) -- | 1,2 |
| Y | <u>US - A - 4 172 295</u> , published 1979, Oct. 30 (BALTEN) -- | 1,2 |

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹¹ not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹², specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ¹³

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

| Category * | Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷ | Relevant to Claims No ¹⁸ |
|------------|--|-------------------------------------|
| Y | <u>US - A - 4 035 849</u> , published 1977, Jul. 19 (ANGELL) -- | 1,2,3 |
| Y | <u>US - A - 3 983 581</u> , published 1976, Oct. 5 (ANGELL) -- | 1,2,3 |
| Y | <u>US - A - 3 755 823</u> , published 1973, Sept. 4 (HANCOCK) ---- | 1,2,3 |